

**Notice of Allowability**

Application No.

10/080,101

Examiner

Jon M. Lockard

Applicant(s)

NIELSEN ET AL.

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**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--**

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to the Amendment filed 15 March 2006.
2. ☒ The allowed claim(s) is/are 1, 4-6, 8-21, 23-25, 39, and 40 (renumbered as claims 1, 2, 3, 5, 6-12, 23, 13-21, 22, and 4).
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some\* c) ☐ None of the:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.  
**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
- (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
- 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
- (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☒ Information Disclosure Statements (PTO-1449 or PTO/SB/08),  
Paper No./Mail Date 12/6/05
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☐ Interview Summary (PTO-413),  
Paper No./Mail Date \_\_\_\_\_.
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other \_\_\_\_\_.

**CHRISTINE J. SAOUD  
PRIMARY EXAMINER**

*Christine J. Saoud*

### EXAMINER'S AMENDMENT

1. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it **MUST** be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Frank Cottingham on 07 June 2006.

The application has been amended as follows:

2. Claims 26-38 have been cancelled without prejudice or disclaimer.
3. In claim 8, the term "polyhydroxypolymer" has been deleted and the term --polyhydroxypolymer carrier-- inserted therefor.
4. In claim 9, the term "polyhydroxypolymer" has been deleted and the term --polyhydroxypolymer carrier-- inserted therefor.
5. In claim 10, the term "polyhydroxypolymer" has been deleted and the term --polyhydroxypolymer carrier-- inserted therefor.
6. In claim 11, the term "polyhydroxypolymer" has been deleted and the term --polyhydroxypolymer carrier-- inserted therefor.
7. In claim 12, the term "polyhydroxypolymer" has been deleted and the term --polyhydroxypolymer carrier-- inserted therefor.
8. In claim 13, the term "polyhydroxypolymer" has been deleted and the term --polyhydroxypolymer carrier-- inserted therefor.

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9. In claim 14, the term "polyhydroxypolymer" has been deleted and the term --polyhydroxypolymer carrier-- inserted therefor.
10. In claim 15, the term "polyhydroxypolymer" has been deleted and the term --polyhydroxypolymer carrier-- inserted therefor.
11. In claim 16, the term "polyhydroxypolymer" has been deleted and the term --polyhydroxypolymer carrier-- inserted therefor.
12. In claim 21, the phrase "and the at least" has been deleted and the phrase --first and-- inserted therefor.
13. In claim 24, the phrase "pharmacologically an immunologically" has been deleted and the phrase -- pharmacologically and immunologically -- inserted therefor.
14. In claim 25, the phrase "such as a toxin, a cytokine and a mycobacterial derivative" has been deleted.
15. In claim 25, the term "a particle" has been deleted and the phrase --an ISCOM particle-- inserted therefor.
16. In claim 39, the term "polyhydroxypolymer" has been deleted and the term --polyhydroxypolymer carrier-- inserted therefor.

#### ***Election/Restrictions***

17. The restriction requirement between the species of polyhydroxypolymers, as set forth in the Office Action mailed on 13 November 2003, has been reconsidered in view of the allowability of claims to the elected invention pursuant to MPEP § 821.04(a). The restriction requirement between the species of polyhydroxypolymers is hereby withdrawn. Claims 9 and

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13, directed to species of polyhydroxypolymers, are no longer withdrawn from consideration because the claim(s) requires all the limitations of an allowable claim.

18. In view of the above noted withdrawal of the restriction requirement as to the linked species, applicant(s) are advised that if any claim(s) depending from or including all the limitations of the allowable generic linking claim(s) be presented in a continuation or divisional application, such claims may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Once a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. See *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

### ***Reasons for Allowance***

19. The following is an examiner's statement of reasons for allowance: The rejections under 35 U.S.C. § 102 and § 103 are withdrawn as the prior art does not teach or suggest the independent coupling of epitopes (B-cell epitopes, CTL epitopes, TH epitopes, or otherwise), via the nitrogen atoms at their respective N-termini, to an activated polyhydroxypolymer carrier.

20. Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

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***Advisory Information***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Jon M. Lockard, Ph.D.** whose telephone number is **(571) 272-2717**. The examiner can normally be reached on Monday through Friday, 8:00 AM to 6:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Brenda Brumback**, can be reached on **(571) 272-0961**.

The fax number for the organization where this application or proceeding is assigned is **571-273-8300**.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see **<http://pair-direct.uspto.gov>**. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at **866-217-9197** (toll-free).

Jon M. Lockard, Ph.D.  
June 7, 2006

**CHRISTINE J. SAOUD  
PRIMARY EXAMINER**

*Christine J. Saoud*